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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,045	02/27/2004	Kathy Forrester	517427-2010.1	6769

20999 7590 07/26/2006

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EXAMINER

REIFSNYDER, DAVID A

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,045

Applicant(s)

FORRESTER, KATHY

Examiner

David A. Reifsnnyder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I claims 1-17 and 20 in the reply filed on June 16, 2006 is acknowledged.

Claim 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 16, 2006.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application-by-application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the oath improperly claims benefit under 35 U.S.C 119 (e) of U.S. Application Ser. No. 09/054,054. (i.e. only a provisional application can claim benefit under 35 U.S.C 119 (e)).

Information Disclosure Statement

The listing of references on page 1, paragraph [0011] of the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be

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submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The following is a quotation of 37 CFR 1.71(a):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

The specification is objected to under 37 CFR 1.71 (a) because of the use of the trademark Nycodenz ® in the specification while the use of trademarks in the specification is permissible, the trademark needs to be capitalized wherever it appears and be accompanied by the generic terminology. Furthermore, Nycodenz ® is not extremely well known trademark; therefore without the inclusion of the generic terminology for the trademark Nycodenz ®, it is vague and indefinite as to what Nycodenz ® is.

The disclosure is also objected to because of the following informalities: Page 1, paragraph [0001] of the specification states; "Reference is made to U.S. Application Ser. No. 09/054,054, filed Nov 27, 2001, the contents of which are expressly incorporated by reference". That statement is vague and indefinite as to how U.S. Application Ser. No. 09/054,054 relates to the present application. Furthermore, the continuity data for U.S. Application Ser. No. 09/054,054 needs to be updated, because U.S. Application Ser. No. 09/054,054 has published as Publication Number: U.S. 2005/0176571 A1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9, are rejected under 35 USC 112, 1st paragraph for the reasons given above in the objections under 37 CFR 1.71. Furthermore, trademarks should not be in the claim at all, only the generic terminology for the trademark should be in the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1; the recitation of "the flow" lacks antecedent basis. Furthermore, it is vague and indefinite as to what is meant by "the flow". (i.e. the flow of what?)

Regarding claim 10 and 11; the recitation in claims 10 and 11 of "the continuously flowing liquid" lacks antecedent basis. Furthermore, it is vague and indefinite as to what is meant by "the continuously flowing liquid". (i.e. what liquid is continuously flowing?)

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Regarding claim 12; the recitation of "the flow rate" lacks antecedent basis. Furthermore, it is vague and indefinite as to what is meant by "the flow rate". (i.e. the flow rate of what?)

Regarding claim 13; the recitation of "wherein the fractions are collected using air pressure" is vague and indefinite because a step of collecting the fractions was never claimed.

Regarding claim 14; the recitation of "wherein the fractions are collected using water pressure" is vague and indefinite because a step of collecting the fractions was never claimed.

Regarding claims 15 and 16; the recitation of "the collection of the fractions" lacks antecedent basis because a step of collection the fractions was never claimed in claims 13 and 14, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunier et al.

Regarding claims 1-17 and 20; Saunier et al. discloses a method of scalable purification of adenoviral preparations, comprising the steps of:

- a) culturing host cells comprising adenovirus, thereby obtaining supernatants from the host cells;
- b) applying said supernatants to a centrifugal apparatus comprising a Nycodenz or Sucrose gradient solution; and
- c) applying centrifugal force to said supernatants to separate the adenoviral particles according to their density, thereby obtaining high-yield fractions of adenoviral particles. (paragraph [0053])

Regarding claims 1-17 and 20; Saunier et al. discloses the claimed invention except for his Sucrose or Nycodenz gradient solution being about 50% w/v. It is considered that it would have been obvious to one having ordinary skill in the art at the time the invention was made, that Saunier et al.'s Nycodenz or Sucrose gradient solution be any desired strength, (e.g. about 50% w/v) because it was known in the art for gradient solutions to be any desired strength (i.e. weight/volume).

Claims 1-6, 10-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 284 287 A1.

Regarding claims 1-6, 10-17 and 20; EP 1 284 287 A1 discloses a method of scalable purification of adenoviral preparations, comprising the steps of:

- a) culturing host cells comprising adenovirus, thereby obtaining supernatants from the host cells; (paragraph [0016], lines 27-28)
- b) applying said supernatants to a centrifugal apparatus comprising a Sucrose gradient solution; (paragraphs [0025] and [0044]) and
- c) applying centrifugal force to said supernatants to separate the adenoviral particles according to their density, thereby obtaining high-yield fractions of adenoviral particles. (paragraphs [0025] and [0044])

Regarding claims 1-6, 10-17 and 20; EP 1 284 287 A1 discloses the claimed invention except for his Sucrose gradient solution being about 50% w/v. It is considered that it would have been obvious to one having ordinary skill in the art at the time the invention was made, that EP 1 284 287 A1's Sucrose gradient solution be any desired strength, (e.g. about 50% w/v) because it was known in the art for gradient solutions to be any desired strength (i.e. weight/volume).

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 284 287 A1 in view of Saunier et al.

Regarding claims 7-9; as discussed above, EP 1 284 287 A1 suggests the instantly claimed method of scalable purification of adenoviral preparations; however,

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EP 1 284 287 A1 fails to suggest using a Nycodenz gradient solution instead of a Sucrose gradient solution.

Regarding claims 7-9, as discussed above, Saunier et al. suggest the instantly claimed method of scalable purification of adenoviral preparations as discussed above including using either a Sucrose or Nycodenz gradient solution.

It is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention, that EP 1 284 287 A1's gradient solution be a Nycodenz gradient solution as taught by Saunier et al., because EP 1 284 287 A1 and Saunier et al. teach similar methods of scalable purification of adenoviral preparations.

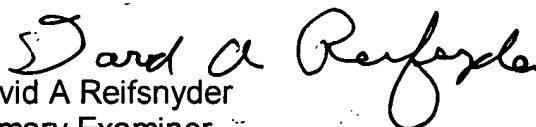
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Reifsnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David A Reifsnyder
Primary Examiner
Art Unit 1723

DAR